



Medicines & Healthcare products Regulatory Agency

MEDICINES RECALL

CLASS 3 MEDICINES RECALL, EL(25)A/30

Action within 5 days

Issued 30 June 2025

Distribute to Pharmacy/Wholesaler Level

MARKETING AUTHORISATION HOLDER (MAH)

Glenmark Pharmaceuticals Europe Ltd

MEDICINE DETAILS

Omeprazole 20 mg/15 ml Oral Solution

PL: 25258/0383

Active Ingredient: Omeprazole

SNOMED code: 42444511000001102

AFFECTED LOT BATCH NUMBERS

Batch No.	Expiry Date	Pack Size	First Distributed
3230528	30/09/2025	14	29/01/2024

Background

Glenmark Pharmaceuticals Europe Ltd is recalling a specific batch of Omeprazole Oral Solution as a precautionary measure due to an investigation following a customer complaint indicating precipitation and discoloration of the product in the bottles. A root cause has identified that this is a result of an inadequate assembly of the plunger stem and the cup which could lead to a premature mixing of the two components of the medicinal product.

Advice for Healthcare Professionals:

Stop supplying the above batch immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.

Advice for Healthcare Professionals to Provide to Patients:

No further action is required by patients as this is a Pharmacy and Wholesaler level recall. Patients should continue to take medicines from these batches as prescribed by your healthcare professional.

Patients who experience adverse reactions or have any questions about the medication, should seek medical attention. Any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#).

Additional information:

For medical information enquiries please use the following options by phone +44 08004 580 383 or email medical_information@glenmarkpharma.com

For stock control enquiries please email orders.uk@glenmarkpharma.com

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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